

continued examination pursuant to §1.114.

**Claim Rejections - 35 USC § 102**

- (1) Claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al (US 5,447,724).

Helmus was cited for teaching all the claimed subject matter including an implantable medical device (col. 3, lines 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 56) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46), wherein the drug makes up 2% by weight of the material (col. 7, lines 57-62).

Helmus' col. 7, lines 57-62, were also noted in the rejection as indeed to specify the OUTER layer, not the reservoir layer. In col. 7, lines 57-62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir layer. The rejection contended that since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col. 6, line 55) is interpreted as referring to physiologically active agents in BOTH the reservoir and outer layer.

Applicants' respectfully traverse. "A claim is anticipated only if ~~each and~~ every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131, citing *Verdegaal Bros. v. Union Oil Col of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Helmus does not expressly claim that the tissue-contacting polymer surface of the catheter is intimately mixed with the drug. Applicants thus interpret that the rejection was based on finding of inherent description in Helmus.

Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not

sufficient." *Crown Operations Int'l, Ltd. v. Souutia Inc.*, 289 F.3d 1367, 1377, 62 USPQ2d 1917 (Fed. Cir. 2002) (citing omitted). Accordingly, the mere fact that Helmus' outer layer agent can be the same as the inner layer agent is not sufficient to anticipate applicants' claims. Instead, in accordance with the case law interpretation such as in *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999), applicants' claims (e.g., tissue-contacting surface of the catheter comprises a polymer in which a steroidal agent is intimately mixed) have to be demonstrated to necessarily be present in Helmus. In other words, "there must be a teaching or suggestion" in Helmus, "within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention..." *Crown Operations Int'l, Ltd.*, 289 F.3d at 1376 (citing omitted).

First, the limitation "intimately mixed agent" would teach away from Helmus. Helmus teaches a pore structure of surface-contacting layer (i.e., outer layer) defines metering outward passages constructed to control the outward migration of the agent from the reservoir (i.e., inner layer) (col. 1, lines 39-46; col. 1, lines 51-54; col. 3, lines 20-22; col. 5, lines 40-42; col. 5, lines 49-51; col. 5, lines 66-68; col. 7, lines 4-6; and Figs. 1a, 1b, 1c, 2a, 2b, and 2c). "Intimate mixing" would result homogenous disperse of the agent and ultimately destroy Helmus' passage concept. In other words, the limitation "intimate mixing" is not only unnecessary but also likely undesirable in Helmus. It would be also contrary to one of the ordinary skill in the art to practice "intimate mixing of the agent" when the result could destroy the intended structure and purpose.

Moreover, thermal methods are undesirable or less desirable approaches for ultimate mixing of the agents in Helmus or in the present application. Processing conditions (mainly heat, pressure, shear stress) of the thermal methods, e.g., Helmus' disclosure of thermal extrusion or molding (col. 4, lines 20-24) and injection molding (col. 9, lines 45-46), tend to degrade or even decompose those agents. It, therefore, would be contrary to one of the ordinary skill in the art to interpret Helmus' thermal methods as either expressed or inherent limitation of "intimate mixing."

Even if, hypothetically, there might be a non-disclosed low-temperature low-pressure thermal extrusion or injection molding that could ultimately achieve

a result of "intimate mixing," mere fact that a certain thing may result from a given set of circumstance is not sufficient as anticipation. As discussed above, Helmus does not teach nor suggest such a limitation.

In summary, the claim "tissue-contacting surface of the catheter comprises a polymer in which a steroidal agent is intimately mixed" is not expressly nor inherently disclosed in Helmus. Applicants thereby respectfully, request removal of the present rejection, and claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 be allowed to issue.

**Claim Rejections - 35 USC § 103**

- (1) Claims 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724).

The rejection noted that Helmus teaches all the claimed subject matter except for the slightly lower concentrations in claims 37 and 43. Helmus was also cited for teaching 2% of the material is the drug, whereas the (present) claims call for a maximum of 1 %. The rejection further stated that in a tissue-contacting wall of a catheter, the amounts of a drug that are needed to achieve a desired release rate vary somewhat based on the specific material that the drug is being mixed into, and also how the catheter was formed (i.e. extrusion process, etc.). The examiner then took the position that it would have been obvious to one of ordinary skill in the art to vary the weight percentage of a drug such a small amount in order to achieve a desired release rate depending the polymer being used and the manufacturing on process (temperature, curing, etc) used to make the catheter.

Applicants respectfully traverse. Helmus teaches that the elutable component in the outer layer may be physiologically active agent (col. 7, lines 57-59). More particularly, it is preferred to incorporate a minor amount, for example, about 2% by weight (col. 7, lines 60-62). The 0.1% - 1% agent in the present claims equates to 50% to 95% below Helmus' teaching. It does not appear to be obvious to one of ordinary skill in the art to further reduce the agent by 50% to 95% when the 2% has already been stated as "a minor amount."

Not Only that  
Furthermore, as discussed above and also noted in the rejection, the agent in Helmus' outer layer is there to form pores and passages. It would not be obvious to one of ordinary skill in the art nor there is incentive to modify the 2% content when modification would destroy the structure and purpose of pores and passages.

Therefore, it does not appear obvious in light of Helmus to have a steroidal agent between 0.1% and 1%. Applicants thereby respectfully request claims 37 and 43 be allowed to issue.

(3) Claims 17-18 (88, p. 44)  
are allowable over Helmus.  
(2) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chait (823)  
(US 5,727,555) in view of Helmus et al (US 5,447,724).

Chait was cited for teaching a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. However, Chait lacks a layer with anti-inflammatory agent in it. Helmus was also found to teach an elongate body-inserted member with an anti-inflammatory agent imbedded in the tissue-contacting surface as discussed supra. The rejection then contended that it would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Helmus in order to reduce inflammation in the treatment area, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

Applicants respectfully traverse. The mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. See MPEP 2143.01, citing *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000).

Chait teaches a catheter having an external fitting coupled to the proximal end and helical coils, said helical coils to be reformed against an interior surface of the body cavity (col. 2, lines 10-24), and intends to solve the problem of accidental dislodge during application (abstract). Chait, however, does not teach or suggest use of the active agent intimately mixed with polymer in its catheter having helical coils. In comparison, Helmus teaches using physiologically active agents to prevent adverse reactions to the device, but does not teach or suggest

WELL  
KNOWN  
to put  
drug in  
surface

use helical coils to prevent dislodge of the device. Therefore, there is no suggestion or incentive for modifying Chait, Helmus, or combination of two to form applicants' claim 14. Likelihood of combining Chait and Helmus would be speculative or random occurrence. "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *Crown Operations Int'l, Ltd.* 289 F.3d at 1376 (Fed. Cir. 2002). Applicants thus respectfully request the present rejection to claim 14 be removed, and claim 14 be allowed to issue.

- (3) Claims 17-19, 38, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al (US 5,609,629).

Helmus was cited for teaching all the claimed subject matter except for the steroid being a glucocorticosteroid such as dexamethasone. Fearnot was cited for teaching the use of dexamethasone in a drug embedded outer layer of a catheter. The rejection then contended that it would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 56) since dexamethasone is a well known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

The rejection also cited the definitions for "cortisone" and "glucocorticoid" from Stedman's medical Dictionary to demonstrate that Helmus teaches an "anti-inflammatory" steroid.

Applicants again respectfully traverse. The mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. See MPEP 2143.01, citing *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). The proposed modification cannot change the principle of operation of a reference. MPEP 2143.01 citing *In re Ratti*, 270 F.2d 810 (CCPA 1959).

As mentioned above, the principle of operation of Helmus' outer layer, even if a physiologically active agent (e.g., glucocorticosteroid) shall be used, consists of pores for passages. Likewise, the principle of operation of Fearnot is to

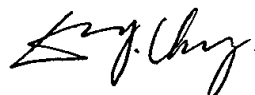
use a porous coating layer over the bioactive layer. Not only neither Fearnot nor Helmus suggests use anti-inflammatory agent on the tissue-contacting surface in form of intimate mixture with polymers, but also such modifications would change the principles of operation of Helmus and Fearnot.

Applicants therefore respectfully request the present rejection over Helmus in view of Fearnot be removed and the claims 17-19, 38, and 44 be allowed to issue.

**Summary**

Applicants believe their present response address the outstanding issues presented by the examiner and respectfully request the finality of office action be withdrawn and all pending claims be allowed to issue.

Respectfully submitted,



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